Health Canada
Pest Management Regulatory Agency

Santé Canada
Agence de réglementation de la lutte antiparasitaire

PRVD2007-05

PROPOSED RE-EVALUATION DECISION

The Use of Dicamba in Agricultural and Industrial Sites

(publié aussi en français)

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

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FOREWARD

Proposed Re-evaluation Decision for Dicamba

Previously, Health Canada's Pest Management Regulatory Agency (PMRA) completed an assessment of the lawn and turf uses of the herbicide dicamba. Details are available in Proposed Acceptability for Continuing Registration document PACR2007-02, *Re-evaluation of Dicamba for Lawn and Turf Uses*.

The PMRA has now reviewed the available information on use of dicamba in industrial sites for vegetation control and in agriculture. Under the authority of the *Pest Control Products Act*, the PMRA is proposing the continued registration of all currently registered uses of dicamba and its end-use products with the implementation of additional mitigation measures to further protect human health and the environment.

This Proposed Re-evaluation Decision (previously called a Proposed Acceptability for Continuing Registration [PACR] document) is a consultation document[1] that summarizes the science evaluation for the remaining uses of dicamba. It also describes risk-reduction measures that will be required to further protect human health and the environment

The proposed mitigation measures for non-turf uses of dicamba include the following:

- a phase-out of the diethanolamine (DEA) form of dicamba unless further data are provided;
- a new maximum application rate of 0.01 kg a.e./L a maximum spray liquid concentration of 0.01 kg a.e./L when high-volume handwands are used for non-cropland applications;
- buffer zones to protect terrestrial habitat; and
- specified or upgraded personal protective equipment, grazing restrictions and preharvest intervals.

The PMRA will accept written comments on this proposal to continue all uses of dicamba up to 60 days from the date of publication of this document. Please forward all comments to Publications (contact information indicated on the cover page of this document). Comments already received in response to the turf review will also be considered in a final decision for all uses of dicamba.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

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1.0 Purpose

This document describes the proposed outcome of the PMRA's re-evaluation of the herbicide dicamba and its end-use products for use in agriculture and for the maintenance of industrial sites. This document follows and supplements a previous assessment of the turf uses of dicamba published this year. This re-evaluation was completed as part of the PMRA's commitment to review pesticides registered prior to 1995, as indicated in Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*.

2.0 Background

2.1 The PMRA's Review of the Turf Uses of Dicamba

Proposed Acceptability for Continuing Registration document PACR2007-02, *Re-evaluation of Dicamba for Lawn and Turf Uses,* was released earlier this year for a 60-day comment period. That document includes the following items:

- an assessment of dicamba when used on lawn and turf;
- a history of the registration of dicamba in Canada;
- a review of the chemistry of dicamba;
- an extensive review of the human toxicology;
- a dietary risk assessment; and
- an aggregate assessment of the risk of human exposure to food, drinking water and residential exposures.

2.2 Scope of this Review

Appendix I lists all dicamba products that are registered with the PMRA, but excludes products registered for use on fine turf only. Appendix II lists all the uses for which dicamba is presently registered (excluding the use on fine turf). All uses of dicamba listed in Appendix II are supported by the registrants and were considered in the health and environmental risk assessment.

Uses of dicamba included in this review are in the following use-site categories: Terrestrial Feed Crops, Terrestrial Food Crops, Industrial and Domestic Vegetation Control Non-food Sites.

This review also considers use of dicamba in the maintenance of utility turf, also known as rough turf in industrial sites. Utility turf at these sites is primarily intended for soil stabilization, requires less maintenance than fine turf and is usually maintained with commercial class products and equipment intended for large-scale application. Industrial sites include roadsides; rights-of-way for railways, hydro installations, pipelines and highways; highway interchanges; airports; wasteland; and industrial parks. In contrast, the re-evaluation of the lawn and turf uses of dicamba (PACR2007-02) focused on assessing the risks resulting from the treatment of fine turf, including sports and recreational turf, lawn turf and sod for transplanting, that is maintained by homeowners or by professional applicators.

2.3 Forms of Dicamba

Dicamba is a Resistance Management Group 4 (synthetic auxins) herbicide, which mimics the natural plant hormone indole-3-acetic acid (auxin) and leads to severe and uncontrolled cell growth, disintegration of phloem, cortical cells and xylem tissues. It works by systemic action.

Dicamba herbicides are active in the acid form, but are formulated as amine or sodium salts to enhance the ability of dicamba acid to enter into the plant. Dicamba is absorbed through leaves, roots and stems, and moves throughout the plant.

For dicamba herbicides, the parent acid is what binds to the herbicide target site within the plant and causes plant death, while the amine, sodium or potassium portion plays no direct role in herbicidal activity. Therefore, when assessing dicamba, the application rates were expressed in terms of the amount of acid equivalent per hectare (e.g. kg a.e./ha).

Other differences in the various forms of dicamba will be explained in the mammalian toxicology as well as the environmental toxicology and fate sections of this review. The names of the various forms of dicamba for use on agricultural and industrial sites are listed in Table 2.3.1.

Table 2.3.1 Forms of Dicamba Included in this Assessment

Grouping	Form
Parent compound	Dicamba acid
Salts	Diethanolamine (DEA)
	Dimethylamine (DMA)
	Diglycolamine (DGA)
	Isoproponylamine (IPA)
	Sodium (Na)
	Potassium (K)

3.0 Re-evaluation of the Agricultural and Industrial Site Uses of Dicamba

3.1 Identity of the Active Substance

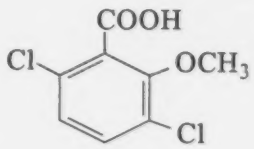
Active substance	Dicamba
Function	Herbicide
Chemical names	
International Union of Pure and Applied Chemistry (IUPAC)	3,6-dichloro-o-anisic acid
Chemical Abstracts Service (CAS)	3,6-dichloro-2-methoxybenzoic acid
CAS number	1918-00-9
Molecular formula	$C_8H_6Cl_2O_3$
Molecular weight	221.0
Structural formula	

Table 3.1.1 Registration Number, Purity and Registrant for the Technical Grade Active Ingredient

Registration Number	Purity of Technical Grade Active Ingredient (%)	Registrant
19290	86.1 (limits: 82.0–91.0)	BASF Canada, Inc.
26613	86.1 (limits: 83.5–88.7)	Syngenta Crop Protection Canada, Inc.
26718	98.3 (limits: 95.4–99.9)	Gharda U.S.A., Inc.

3.2 Physicochemical Properties of Dicamba Substance and Interpretation

Property	Result	Interpretation
Vapour pressure	1.67 mPa (25°C, calculated) 3.4×10^{-5} mm Hg at 25°C	Slight potential for volatilization
Henry's law constant	6.1×10^{-5} Pa m^3 mol^{-1} 5.99×10^{-10} atm m^3 mol^{-1}	Low potential to volatilize from water or moist sediment
Ultraviolet (UV)–visible spectrum	Not expected to show significant UV absorption at wave length > 350 nm.	Not likely to be susceptible to direct phototransformation
Solubility in water at 25°C	6.1 g/L (25°C)	Very soluble
n-Octanol–water partition coefficient (log K_{ow})	**pH** **log K_{ow}** 5.0 -0.55 6.8 -1.88 8.9 -1.9	Unlikely to bioaccumulate
Dissociation constant	pK_a = 1.97	Potentially mobile at environmental pH

4.0 Effects Having Relevance to Human Health

4.1 Toxicology Summary

Based on an assessment of the limited data available on the toxicological equivalencies of different forms of dicamba, it is considered that the acid and DMA forms of dicamba are toxicologically equivalent. It is anticipated that the sodium salt of dicamba dissociates into dicamba acid and the relatively non-toxic sodium moiety and is toxicologically equivalent to dicamba free acid. Other forms of dicamba registered for agricultural uses include dicamba IPA, DGA and DEA.

Limited toxicology data with DGA and IPA forms of dicamba were available at the time of this review. Metabolism data with IPA and DGA show rapid dissociation to the acid form and respective moiety with no significant differences from the acid form with respect to absorption, distribution, metabolism and excretion. Based on an assessment of the available data, the IPA and DGA forms are considered to have comparable acute oral toxicities to the acid. With acute dermal exposure, the IPA and DGA forms show similar low toxicity as the acid form. With respect to acute inhalation exposure, the IPA and DGA forms cannot be compared to the acid form due to the lack of an adequate acute inhalation study conducted with the free acid. However, the IPA, DGA and DMA forms all show low acute toxicity by this route. The IPA and DGA forms are considered to be of less or comparable toxicity with respect to irritation and sensitization. With repeat-dose dermal studies in the rabbit, the IPA and DGA forms show similar low toxicity as the acid form. Although definitive comparisons of toxicological

equivalency are hindered by dose limitations, the occurrence of dermal toxicity with dicamba acid at lower levels of acid equivalents (a.e.) than seen with the IPA and DGA forms support the use of the dicamba acid database as a suitable surrogate for these forms. Both IPA and DGA are considered List 3 formulants and have no identified health concerns at this time.

There was no toxicological information on the DEA form of dicamba. However concerns arise from published literature showing repeated dermal application of DEA on its own is carcinogenic in mice. No tumours were evident in a similar study conducted in rats, although the doses used were lower than those used in the mouse studies. Short-term oral and dermal studies also indicate that pure DEA causes brain and spinal cord demyelination in rats and is immunotoxic in rats and mice. DEA is also identified as a List 2 formulant (potentially toxic formulants, with a high priority for testing). DEA demonstrated greater systemic toxicity than dicamba. Based on the apparent difference in toxicological profile for DEA on its own, relative to dicamba acid and other dicamba forms, further assessment for dicamba DEA was not possible and regulatory actions are therefore proposed (see Section 8.1).

In laboratory animals, dicamba has low acute toxicity via oral and dermal routes. No adequate acute inhalation study is available. Dicamba is corrosive to the eyes, a dermal irritant and a potential skin sensitizer. Repeat-dose oral exposure resulted in liver effects, alterations in clinical chemistry as well as decreases in body-weight gain and food consumption. In repeat-dose oral studies, the dog appeared to be the most sensitive species. A comparison of data from dog studies of different durations (two months to one year) suggests that toxicity increases with length of exposure. Given the lack of information from other species upon which to establish species-specific relationships between duration of exposure and toxicity, it is assumed that the increased toxicity that accompanies increased length of exposure in the dog is not unique to this species. Despite the presence of behavioural neurotoxic indicators in several studies, a subchronic neurotoxicity study revealed few signs of neurotoxicity and only at very high dose levels.

Dicamba did not cause fetal malformations in rats or rabbits, and the developmental studies did not demonstrate any sensitivity of the young relative to adult animals. In reproductive studies, offspring appeared to be more sensitive than parental animals to the toxic effects of dicamba. Decreased birth weight was observed in all litters from two generations in the absence of any prenatal indicator of parental toxicity. As no similar sensitivity of the young was observed under the short-term exposure scenario of the developmental studies, sensitivity of the young to dicamba was thought to be associated with prolonged exposure of the maternal animal. Furthermore, sensitivity of the young was considered to result from indirect (i.e. in utero) exposure because effects were noted at birth. Parental effects were almost exclusively limited to the first filial (F_1) generation suggesting that the F_1 generation developed a higher sensitivity to dicamba which may be due to in utero exposure.

Findings from several different studies suggest effects on the endocrine system. In the two-generation rat reproduction study, a dose-related decrease in sperm motility was seen. This is consistent with an absence of spermatozoa in the epididymides noted in the chronic mouse study. Additionally, inflammation of the prostate was seen in the one-year dog study, and a delay in preputial separation was seen among F_1 males in the rat reproduction study. With the possible

exception of delayed preputial separation, these findings cannot be considered definitive due to a variety of factors (e.g. lack of dose response, low animal numbers, age of animals, absence of incidence data, etc.); however, these findings cannot be discounted on the basis of any other existing data.

The weight of evidence from in vitro microbiological mutagenicity assays suggests that dicamba is not genotoxic, though some assays in the literature reported positive results for genotoxicity. These positive results indicate that dicamba may cause DNA damage in bacteria and yeast. Dicamba was found to be negative in an in vivo chromosomal aberration study in the rat.

In the two-year dietary carcinogenicity studies in the mouse and the rat, there was no evidence of dicamba being carcinogenic. However, the rat study was deemed inadequate as an assessment of the carcinogenic potential/chronic toxicity of dicamba because the highest dose tested (107 mg/kg bw/day) did not elicit any effects and was below the maximum tolerated dose (in other studies, rats received approximately four-fold the high dose used in the rat carcinogenicity study and exhibited only minor effects). In light of the inadequacy of the repeat-dose carcinogenicity study and the presence of several positive in vitro genotoxicity results, conclusions that dicamba is non-carcinogenic cannot be considered definitive. However, the weight of evidence suggests that dicamba is unlikely to be genotoxic or carcinogenic at potential environmental or occupational exposure levels. Furthermore, the subsequent dietary risk assessment incorporates substantial margins of safety from the highest dose tested (no observed adverse effect level [NOAEL]) in the rat carcinogenicity study, which was negative for carcinogenicity.

Route-specific reference doses have been set on the general toxicological parameters affected in the various studies. These reference doses incorporate various uncertainty factors to account for extrapolating between laboratory animals and humans, for variability within the human population and for data gaps. Additional safety factors have also been employed, where warranted, to protect pregnant females and their unborn children due to potential sensitivity concerns arising from in utero exposure. Sensitivity of the offspring concerns were only considered relevant to non-acute risk assessments because effects indicative of sensitivity of the young were attributed to prolonged repeated dosing of the maternal animals.

4.2 Occupational and Bystander Residential Risk Assessment

Occupational risk is estimated by comparing the potential exposure of persons mixing, loading and applying pesticides to the most relevant endpoints from toxicology studies to generate a margin of exposure (MOE). The risk exceeds the PMRA's level of concern if the obtained MOE is less than the desired target MOE.

For short-term dermal risk assessments (>1 day to 6 weeks), the most relevant studies are three 3-week dermal studies in the rabbit. A NOAEL for systemic effects of 1000 mg/kg bw/day (the highest dose tested) was selected from one study, while the two other studies had lowest observed adverse effect levels (LOAELs) of 2500 mg/kg bw/day (the highest dose tested). Effects at this dose level consisted of increased blood glucose; and decreased body weight, urine pH, hemoglobin and total protein. When considered together, these three dermal studies offer a

consistent toxicological picture that is corroborated by observed dermal absorption values. In light of the sensitivity observed in the rat reproduction study, an additional safety factor is required to ensure protection of the pregnant female. For > 1-day to 6-week exposures, a target MOE of 300 from the systemic NOAEL of 1000 mg/kg bw/day was selected. This MOE is based on standard uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and an additional 3-fold safety factor to account for potential sensitivity of the young. This assessment is considered protective of all worker populations.

The risk assessment for intermediate-term dermal exposure (> 6 weeks to several months) is based on the same endpoint as in the short-term dermal risk assessment—a NOAEL of 1000 mg/kg bw/day from three-week dermal rabbit studies. A target MOE of 1000 was selected based on standard uncertainty factors of 10 for interspecies extrapolation and 10 for intraspecies variability as well as an additional 10-fold factor. The additional 10-fold factor was added to account for sensitivity of the young (discussed previously) and the extrapolation of short-term study results to a longer-term scenario.

For the short-term inhalation risk assessments (> 1 day to 6 weeks), no suitable inhalation studies are available; thus, the assessment defaults to the use of oral studies as a surrogate. A maternal NOAEL of 30 mg/kg bw/day from the rabbit oral developmental study and a target MOE of 300 were selected. The target MOE of 300 is based on standard uncertainty factors of 10-fold for intraspecies variability, 10-fold for interspecies variability as well as an additional 3-fold safety factor for potential sensitivity in the young.

For intermediate-term inhalation risk (> 6 weeks to several months), the assessment is based on the NOAEL of 11.2 mg/kg bw/day from the 1-year dog study. A target MOE of 300 was selected based on standard uncertainty factors of 10-fold for intraspecies variability, 10-fold for interspecies variability and an additional 3-fold safety factor for potential sensitivity of the young.

A summary of the toxicology endpoints are presented in Appendix III.

4.2.1 Occupational Exposure and Risk Assessment

Workers can be exposed to dicamba when mixing, loading or applying the pesticide and when entering a treated site to conduct activities such as handling treated crops.

4.2.1.1 Mixer/Loader/Applicator Exposure and Risk Assessment

There are potential exposures to mixers, loaders, applicators, and other handlers. The following supported uses were assessed.

- Aerial application to barley, canary grass, fallow land, oats, spring rye, stubble, spring wheat, durum wheat, winter wheat and non-cropland
- Groundboom application to barley, lowbush blueberries, canary grass, corn, fallow land, oats, pasture, red fescue, spring rye, seedling grasses, stubble, spring wheat, durum wheat, winter wheat and non-cropland

- Low-pressure handwand and backpack to lowbush blueberries and non-cropland
- High-pressure handwand and right-of-way sprayer to non-cropland

Based on the number of applications, workers applying dicamba would generally have a short-term (1 day to 6 weeks) duration of exposure. The exception would be for non-cropland uses (roadsides, hydro, pipeline and railway rights-of-way, airports, military bases, turf, wasteland), which represent an intermediate-term (6 to 12 weeks) duration of exposure. The PMRA estimated handler exposure based on different levels of personal protective equipment (PPE).

- Baseline PPE: a long-sleeved shirt and long pants, chemical-resistant gloves, with and without respirator with open mixing
- Mid-level PPE: coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, with and without respirator and open mixing
- Maximum PPE: chemical-resistant coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, with respirator and open mixing

Mixer/loader/applicator exposure estimates are based on the best available data at this time. The assessment might be refined with exposure data representative of modern application equipment and engineering controls. Biological monitoring data could also further refine the assessment.

No chemical-specific handler exposure data were submitted for dicamba; therefore, dermal and inhalation exposures were estimated using data from the Pesticide Handlers Exposure Database (PHED), Version 1.1. The PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software that facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of PPE. In most cases, the PHED did not contain appropriate data sets to estimate exposure to workers wearing chemical-resistant coveralls or a respirator. This was estimated by incorporating a 90% clothing protection factor for chemical-resistant coveralls and a 90% protection factor for a respirator into the unit exposure data.

For some scenarios (e.g. hand-held equipment), estimating exposure for mix/load with wettable granules or granules was not possible using PHED. In these situations, mix/load/application with open pour liquid for a low-pressure handwand, a high-pressure handwand and a backpack were used in addition to the open mixing and loading dry flowable unit exposures. It should be noted that PHED scenarios with high- and low-pressure handwand are representative of applying products on low- and mid-level shrubs and may underestimate exposures to the head and upper body for currently assessed brush scenarios (applying on trees).

Calculated MOEs exceed target MOEs for mixing, loading and applying for current label uses provided PPE are used as summarized in Appendix IV and V, with the exception of non-cropland uses with high-pressure handwand (see Appendix VI). Proposed mitigation measures and regulatory actions are described in Section 8.0.

4.2.1.2 Occupational Postapplication Exposure Risk Assessment

Based on the dicamba use pattern, there is potential for short-term (1 day to 6 weeks) postapplication exposure to dicamba residues for workers outdoors. The postapplication occupational risk assessment considered exposures to workers entering treated sites. Dislodgeable foliar residue data are used to estimate postapplication exposure resulting from contact with treated foliage at various times after application. Although dicamba is applied to agricultural areas including terrestrial feed crops, terrestrial food crops and non-cropland areas (roadsides, hydro, pipeline and railway rights-of-way, airports, military bases, turf, wasteland), no relevant dislodgeable foliar residue studies were available. As a result, a conservative default value of 20% of application rate with a 10% dissipation per day was used. Postapplication exposure includes activities such as thinning, pruning, harvesting, training, irrigation and transplanting. It is assumed that exposure is likely to be short-term in duration.

Restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before workers or others can safely enter a treated site. An REI is the duration of time which must elapse before residues and/or air concentrations decline to a level so entry into a treated area to perform a specific activity results in exposures above the target MOE (i.e. > 300). Postapplication exposure calculations for each use site are summarized in Table 4.2.1.2.1 and Appendix VI. REIs are not required because the calculated MOEs were greater than the target MOE for all activities and crops.

Table 4.2.1.2.1 Commercial Postapplication Activities

Crop	Activity	Transfer Coefficient cm²/hour	Dislodgeable Foliar Residue µg/cm²	Dermal Exposure µg/kg bw/day	MOE at Day 0
Use-Site Category 13—Terrestrial Feed Crops **Use-Site Category 14—Terrestrial Food Crops**					
Corn (sweet)	Hand detasseling, hand harvesting	17 000	0.3264	634.11	1577
	Irrigation, scouting, handweeding	1000	0.3264	37.3	26 809
	Scouting (low crop height)	400	0.3264	14.92	67 023
Corn (field)	Irrigation, scouting, handweeding	1000	1.629	186.19	5371
	Scouting (low crop height)	400	1.629	74.48	13 427
Lowbush Blueberries	Hand harvesting, hand pruning	1500	6.858	1175.66	851
	Scouting, hand weeding, irrigation, hand pruning, thinning	400	6.858	313.51	3190

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Crop	Activity	Transfer Coefficient[a] cm^2/hour	Dislodgeable Foliar Residue[b] µg/cm^2	Dermal Exposure[c] µg/kg bw/day	MOE[d] at Day 0
Barley, oats, spring rye, wheat	Scouting, irrigation	1500	0.304	52.11	19 189
	Scouting, irrigation (low crop height)	100	0.304	3.47	287 829
Canary grass, seedling grasses	Scouting, irrigation	1500	0.28	48	20 833
	Scouting, irrigation (low crop height)	100	0.28	3.2	312 500
Stubble fields and fallow land	Scouting, irrigation	1500	2.416	414.17	2414
	Scouting, irrigation (low crop height)	100	2.416	27.61	36 217
Red fescue	Scouting, irrigation	1500	0.58	99.43	10 057
	Scouting, irrigation (low crop height)	100	0.58	6.63	150 862
Use-Site Category 16—Industrial and Domestic Vegetation Control Non-food Sites					
Non-crop areas	Scouting, irrigation	1500	13.056	2238.23	447
	Scouting, irrigation (low crop height)	100	13.056	149.22	6702

[a] Transfer coefficients are from the Science Advisory Council for Exposure.

[b] Dislodgeable foliar residue calculations are based on a default of 20% of the application rate and 10% dissipation per day at a maximum application rate. One application was assumed for all crops except corn (field and sweet) and non-cropland, where two-application scenarios were assessed.

[c] Dermal exposure = dislodgeable foliar residue × transfer coefficient × 8 hour / 70 kg.

[d] Based on the short-term dermal NOAEL of 1000 mg/kg bw/day (target MOE = 300); day 0 represents the last day of application.

4.2.2 Residential Exposure and Risk Assessment

Residential risk assessment is concerned with estimating risks to the general population, including children, during or after pesticide application. Postapplication exposure in turf scenarios were assessed previously (see PACR2007-02).

Crop	Activity	Transfer Coefficient[a] cm^2/hour	Dislodgeable Foliar Residue[b] $\mu g/cm^2$	Dermal Exposure[c] µg/kg bw/day	MOE[d] at Day 0
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4.3 Dietary Exposure and Risk Assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in milk and meat, may be ingested with the daily diet. Exposure to dicamba from potentially treated imports is also included in the assessment. These dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life. For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults. Dietary risk is then determined by the combination of the exposure and the toxicity assessments. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

Residue estimates used in the dietary risk assessment may be conservatively based on the maximum residue limits (MRLs) or the field trial data which is representative of the residues which may remain on food after treatment at the maximum label rate. Surveillance data representative of the national food supply may also be used to derive a more accurate estimate of the residues that may remain on food when it is purchased. These include information from the Canadian Food Inspection Agency National Chemical Residue Monitoring Program and the United States Department of Agriculture Pesticide Data Program.

Acute and chronic dietary exposure and risk estimates were generated using Dietary Exposure Evaluation Model (DEEM®) software and updated consumption data from the United Sates Department of Agriculture's Continuing Survey of Food Intakes by Individuals 1994–1998.

4.3.1 Acute Dietary Exposure and Risk Assessment

Acute dietary risk is calculated considering food consumption and food residue values. A probabilistic statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of dicamba residue that might be eaten in a day. A value representing the high end (95th percentile) of this distribution is compared to the acute reference dose (ARfD), which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake from residues is less than the ARfD, the expected intake is not considered to be of concern.

The dietary ARfD (single day) for all populations is 0.3 mg/kg bw, based on a NOAEL of 30 mg/kg bw/day derived from an oral developmental rabbit study. The LOAEL in this study was 150 mg/kg bw/day and was based on ataxia. The LOAEL from the corresponding range-finding study was 125 mg/kg bw/day and was based on hyper-reactivity, while more varied and severe clinical signs were observed at higher dose levels. Sensitivity of the young was not evident under acute exposure scenarios. A standard 100-fold uncertainty factor is applicable to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold). The ARfD is considered to be protective of all populations. This information is presented in Appendix III.

The acute dietary risk assessment is assessed at the 95th percentile of exposure as the residue estimates are based on the highest field trial result or tolerance, and 100% of the crop is assumed treated. Refined surveillance data was used only in the case of milk. Acute dietary exposure as a percentage of the reference dose is 4.1% for the general population and 7.6% for the most affected population of children 1–2 years of age. The acute exposure to dicamba for all Canadian subpopulations at the 95th percentile is less than the reference dose; therefore, it is below the PMRA's level of concern.

4.3.2 Chronic Dietary Exposure and Risk Assessment

The chronic dietary risk was calculated by using the average consumption of different foods and the average residue values on those foods over a 70-year lifetime. This expected intake of residues was compared to the acceptable daily intake (ADI), which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. When the expected intake from residues is less than the ADI, the expected intake is not considered to be of concern.

The chronic (lifetime) dietary reference dose, or ADI value, for all populations is 0.011 mg/kg bw/day, based on a NOAEL of 11.2 mg/kg bw/day derived from the 1-year dog study. The LOAEL of 58.5 mg/kg bw/day in this study resulted in alterations in clinical chemistry and inflammation of the prostate. Also considered is the two-generation rat reproduction study which demonstrated sensitivity in the young following indirect (in utero) exposure. The lack of an acceptable carcinogenicity study in the rat was also considered, in that the available study was not conducted at dose levels up to the maximum tolerated dose. Standard uncertainty factors of 10-fold for intraspecies extrapolation, and 10-fold for interspecies variability applied. An additional 10-fold safety/uncertainty factor is applied to account for potential sensitivity of the young and the lack of an acceptable carcinogenicity study in the rat, for an overall factor of 1000. This ADI is considered protective of the offspring and would also intrinsically address observations which are potentially related effects on the endocrine system. Although the rat chronic toxicity/carcinogenicity study was not performed at maximum tolerated doses, the ADI does provide a margin of safety of > 9500 to the highest dose tested in this study which was without effect.

The chronic dietary risk assessment was conservatively based on field trial or tolerance level residues for livestock and imported grains. Grain surveillance data was used to estimate residues on domestic grains. As with the acute assessment, surveillance data was used to estimate residues in milk. Chronic dietary exposure as a percentage of the reference dose is 1.3% for the general population to 3.1% for the most affected population of children 1–2 years of age. The chronic exposure to dicamba for all Canadian subpopulations is less than the reference dose; therefore, it is below the PMRA's level of concern.

4.3.3 Drinking Water Exposure

The calculated drinking water levels of comparison (DWLOC) expresses the difference between the reference dose and the non-drinking water exposure and is only be calculated if all other exposures are not of concern to the Agency. The chronic DWLOCs ranged from 163 µg/L for the most affected subpopulation of children 1–2 years of age, to 387 µg/L for the general population. The acute DWLOCs ranged from 4157 µg/L for the most affected subpopulation of children 1–2 years of age, to 10 071 µg/L for the general population.

4.4 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation).

Aggregation of food, water, residential, and other non-occupational sources is addressed in the lawn and turf use PACR document for dicamba (PACR2007-02).

The acute and chronic dietary exposure estimates for all subpopulations are less than the reference doses. The estimated maximum concentration of dicamba in water supplies is not expected to exceed 15µg/L, based on the available surveillance data (see Section 5.3). As this high percentile (97.5^{th}) estimate does not exceed the DWLOC for any population or time period, and as dietary exposure is acceptable, the aggregate exposure to dicamba from food and drinking water is not of concern.

5.0 Environmental Assessment

A deterministic approach was used in assessing the environmental risk of dicamba. In this standard PMRA approach, risk was characterized by the quotient method, the ratio of the estimated environmental concentration to the effects endpoint of concern. Risk quotient (RQ) values less than one are considered to indicate a low risk of non-target effects occurring, whereas values greater than one are considered to indicate that some degree of risk exists for effects on non-target organisms.

For use in a screening-level assessment, initial and cumulative expected environmental concentrations (EECs) were calculated for soil, water and wildlife food sources for dicamba. A range of application rates was used to calculate the EECs. The EECs for multiple applications are cummulative concentrations based on the maximum number of applications, minimum interval between applications and the time for 50% decline (DT_{50}) for the appropriate environmental media (soil, water and food sources). When a risk in aquatic systems was identified in the screening level assessment, the potential risk from drift and runoff were further assessed. The EECs resulting from runoff were predicted using the Pesticide Root Zone Model / Exposure Analysis Modeling System (PRZM/EXAMS). The effects endpoints considered were acute and chronic, chosen from the range of toxicity tests on species available. Effects endpoints, chosen from the most sensitive species, were used as surrogates to represent the wide range of species that could be exposed following treatment with dicamba.

5.1 Environmental Fate

The current assessment considered the DMA salt, DGA salt, IPA salt, sodium salt, potassium salt and acid forms of dicamba. There is evidence the salt forms of dicamba will dissociate rapidly in the environment to the dicamba anion and the associated cation.

The available fate data indicate that dicamba and it's major transformation product 3,6-dichlorosalicylic acid (3,6-DCSA) will be slightly to moderately persistent in the environment. Dicamba was determined to be mobile, whereas there is evidence 3,6-DCSA is not likely to be mobile. Dicamba is highly soluble in water (6069 mg a.i./L) and is unlikely to bioaccumulate (K_{ow} = 0.1). Phototransformation is not an important route of dissipation of dicamba on soil ($t_{½}$ = 201 d) whereas, aerobic soil biotransformation is the major transformation process for dicamba ($t_{½}$ = 2.9 to 21 days). Under anaerobic conditions; biotransformation of dicamba occurs at a slower rate ($t_{½}$ = 84 days) in soil and will play a lesser role in the dissipation of dicamba from the environment. Under field conditions dicamba dissipates with a DT_{50} of 15.4 days and a DT_{90} of 51.2 days. Calculated organic carbon partition coefficients (K_{oc}s) ranging from 3.5 to 21 indicate that dicamba is very mobile in soil and is likely to affect groundwater and surface-water resources. Surface water monitoring for dicamba was provided by Environment Canada through the Pesticide Science Fund and provincial authorities responsible for water monitoring. This monitoring indicates that dicamba is a common active ingredient detected in Canadian surface water. Although, no monitoring data were available for groundwater, dicamba meets all of the criteria for leaching according to Cohen et al. (1984). In addition, the calculated groundwater ubiquity score was 2.77, which classifies dicamba as a boarder-line leacher. Therefore, the PMRA concludes that dicamba has the potential to leach to groundwater.

Volatilization (vapour pressure = 3.4×10^{-5} mm Hg at 25°C) from soil and plant surfaces may contribute to the dissipation of dicamba in the environment which may lead to adverse effects on non-target plants, through redeposition, in the vicinity of the treatment field. Laboratory studies investigating the volatility of dicamba confirm that some dicamba will volatilize from the treatment field and could potentially cause damage to crops in adjacent fields via re-deposition through rain, dry deposition, etc. Dicamba has been detected in ambient air samples in Canada at concentrations up to 1.29 ng/m^3.

The Henry's law constant (5.99×10^{-10} atm m^3/mol) suggests that volatilization from water is not likely to be a significant process contributing to the dissipation of dicamba from the aquatic environment. Dissipation of dicamba from the aquatic environment is not expected to occur by hydrolysis because no transformation occurred in the 30-day laboratory studies. Phototransformation of dicamba in surface waters is not an important route of transformation ($t_{½}$ > 30 day). In water, aerobic biotransformation may be an important process for the dissipation of dicamba from aqueous environments ($t_{½}$ = 39.8–45.5 days in sediment–water systems). These half-lives indicate that dicamba is moderately persistent in water. Anaerobic biotransformation is not likely to contribute substantially to the dissipation of dicamba from aquatic systems ($t_{½}$ = 141 days). Given the high solubility, low K_{oc}s (3.5 to 21.2) and low K_{ow} (0.1), dicamba is likely to dissolve in water rather then be adsorbed to organic particles in the water column.

The major transformation product resulting from biotransformation of dicamba was identified as 3,6-DCSA. 3,6-DCSA is very soluble (2122 mg a.i./L) and appears to be more persistent than the parent compound dicamba. 3,6-DCSA is less mobile than dicamba (K_{oc} = 242–2930) and is unlikely to reach groundwater sources. This transformation product has a low vapour pressure (approximately 10^{-7} mm Hg) and is not expected to volatilize. In addition, 3,6-DCSA is not expected to bioaccumulate as the log K_{ow} was determined to be 0.29. Currently, not enough information is available to fully assess the fate of 3,6-DCSA in the environment.

5.2 Environmental Toxicology

Reported acute toxicity values are the lethal dose to 50% (LD_{50}) of 90.65µg a.e./bee for honeybees and the LD_{50} of 1028 mg a.e./kg bw for small wild mammals. The toxicity of dicamba to birds is the LD_{50} of 1951–188 mg a.e./kg bw on an acute oral basis and the lethal concentration to 50% (LC_{50}) of > 8680 mg a.e./kg diet on an acute dietary basis. Reproductive effects in birds are not expected at dietary concentrations less than the no observed effect concentration (NOEC) of 800 mg a.e./kg diet. Reproductive effects in small mammals are not expected to occur at dietary concentrations less than the NOEC of 500 mg a.e./kg diet determined in a 2-generation reproduction study.

The toxicity of dicamba to plants varies depending on the species. Toxicity endpoints calculated for vegetative vigor varied from the 14-day effect concentration 25% (EC_{25}) of 7.3 g a.e./ha (14-day NOEC < 4.5 g a.e./ha) for soybeans to the 14-day EC_{25} of 2465.9 g a.e./ha (14-day NOEC = 1120.9 g a.e./ha) for ryegrass. For seedling emergence the toxicity endpoints range from the 14-day EC_{25} of 3.0 g a.e./ha (14-day no observed effect level [NOEL] = 2.2 g a.e./ha) for soybeans to the 14-day EC_{25} of 638.9 g a.e./ha (14-day NOEL = 280.2 g a.e./ha) for oats.

The acute toxicity for freshwater invertebrates is reported as the LC_{50} of 110.7 mg a.e./L and the LC_{50} of 135.4 mg a.e./L for fish. Effects to the freshwater diatom (*Navicula pelliculosa*) were not observed at a concentration of 0.50 mg a.e./L. No effects were noted for freshwater algae (*Anabaena flos-aquae*) and the freshwater vascular plant (*Lemna gibba*) at concentrations of 0.0049 mg a.e./L and 0.25 mg a.e./L, respectively.

5.3 Concentrations in Drinking Water

The estimated concentrations of dicamba in potential drinking water sources were determined through the examination of available water monitoring data. Dicamba is detected frequently in water sources, ranging from 10% from known municipal drinking water sources to 50% in ambient water sources that may serve as drinking water and in farm dugouts. The maximum or upper detection value estimated from the monitoring data ranged from 5µg/L in municipal drinking water and ambient water sources and 15µg/L in farm dugouts. A common detection value (one that is most often observed) was determined as 0.5µg/L for municipal drinking water and ambient water sources and 5µg/L for farm dugouts.

5.4 Terrestrial Risk Characterization

No potential risk to honey bees and other pollinating insects was identified in the risk assessment.

Toxicity data were available for the bobwhite quail and the mallard duck for the acid, DMA salt, potassium and DGA salt forms. The data indicate that the toxicity of these forms do not differ.

Birds can be exposed to dicamba by consuming contaminated food (e.g. seeds, insects, vegetation). The toxicity endpoints were extrapolated to smaller bird species that are more likely to be present in the areas where dicamba is applied. The standard PMRA assessment scenario showed it took more than one day of feeding continuously on a contaminated diet to reach the LD_{50}. Feeding solely on contaminated food for more than a day is considered as a conservative exposure scenario. Acute effects in birds are not expected under field conditions. Upon consideration of dietary preference and daily consumption rates, no risk of acute or reproductive adverse effects was identified for wild birds on an acute dietary and reproductive basis.

Mammals can be exposed to dicamba by consuming contaminated food (e.g. vegetation, insects, seeds, etc.). Based on the acute toxicity values and using the standard PMRA scenario, it was determined that it would take longer than one day of continuous feeding on a contaminated diet for small mammals to obtain a dose equivalent to the LD_{50}. Feeding solely on contaminated food from more than a day is considered as a conservative exposure scenario. Acute effects in small wild mammals are not expected under field conditions. Taking into consideration the dietary preference and daily consumption rates, it was concluded small mammals are at low to moderate risk (RQ = 0.1–3.7) of acute effects and low to moderate risk (RQ = 0.2–4.5) of reproductive effects depending on application rates used.

Toxicity data were available for a variety of terrestrial plant species. The most sensitive species was the soybean for vegetative vigour and seedling emergence. Based on the toxicity data for terrestrial plants, and the minimum and maximum application rates for dicamba, risk quotients ranged from 69–2007 for seedling emergence and 21–605 for vegetative vigor; these values indicate the risk of non-target effects resulting from exposure of non-target plants to dicamba is high to extremely high. When considering the impact of drift on terrestrial plants, it was determined that 0.05 and 1.5% of the application would be sufficient to reach the threshold of effects for seedling emergence (NOEC of 2.2 g a.e./ha). When considering the vegetative vigor endpoint (EC_{25} = 7.3 g a.e./ha), the percentage of the application rate that would result in adverse effects ranged between 0.2 and 6%. Given these percentages are less than the application rate, the necessity for spray drift buffer zones were considered (see Section 5.7).

5.5 Aquatic Risk Assessment

The screening level assessment for aquatic organisms indicates that effects threshold concentrations were not exceeded for freshwater invertebrates and fish and estuarine/marine invertebrates. The threshold of effect concentrations was exceeded for freshwater aquatic plants and estuarine/marine plants, based on the screening level assessment; thus, a refined assessment was conducted which considers exposure from run-off and drift.

When considering the percentage of the application rate required to reach the threshold of effects, it was determined that spray drift poses a risk to both freshwater and estuarine/marine plants. Depending on the application rate, it was determined that 0.3 to 9.8% of the application rate would result in EECs that would exceed the threshold of effects for freshwater algae. For estuarine/marine algae the percentage of the application rate that would exceed the threshold of effects was determined to be 0.8 to 22%. Given these percentages are less than the application rate, the necessity for spray drift buffer zones were considered (see Section 5.7).

To assess the risk of exposure to dicamba via runoff, refined EECs were predicted using the PRZM/EXAMS model. For each year of simulation, the model reports daily concentrations as well as averages over various time periods (96-hour, 21-day, 60-day 90-day and 1-year). The 90th percentiles of these values are calculated for use in the assessment. Using the appropriate EECs with the available toxicity data, the risk quotients indicate that freshwater algae are at moderate to high risk (RQ = 3.6–26.3) from exposure to runoff EECs predicted by PRZM/EXAMS. Similarly, estuarine/marine algae are at moderate to high risk from exposure to runoff EECs predicted by PRZM/EXAMS. Monitoring data from Environment Canada and provincial ministries were considered in this assessment. Using the absolute maximum concentration reported (7.8µg a.i./L), it was determined that freshwater algae (RQ = 1.6) are at moderate risk from concentrations detected through monitoring and estuarine/marine algae (RQ = 0.7) are at low risk from monitoring concentrations. It should be noted the monitoring was conducted in freshwater environments and may not represent the concentrations that may be present in estuarine/marine environments. With the nature of monitoring data, it is likely that the maximum concentration was not detected and reported. Therefore, it is likely that higher concentrations of dicamba may be present in the Canadian aquatic environment. Increased frequency of sampling would increase the probability of detecting the peak concentration.

5.6 Environmental Assessment Conclusions

Dicamba has potential to contaminate Canadian surface waters due to its high mobility. There is evidence that dicamba may volatilize and could cause toxic effects to plants in neighbouring crops/fields due to localized redeposition.

Dicamba poses a potential risk to terrestrial and aquatic plants through exposure via both drift and runoff.

5.7 Environmental Risk Mitigation

Dicamba can enter non-target terrestrial and aquatic ecosystems through spray drift. Observing spray buffer zones, however, can effectively mitigate the risk to off-site non-target organisms. The extent of pesticide spray drift from ground application to habitats of concern was predicted using the data of Wolf and Caldwell (2001). Based on the spray drift predictions and the most sensitive toxicity endpoint, buffer zones were calculated for mitigating the entry of dicamba into terrestrial and aquatic habitats. The most sensitive toxicity endpoints used in calculating buffer zones are the NOEC of 0.0049µg a.i./L (*Selenastrum capricornutum*) for aquatic habitats and the EC_{25} of 3 g a.i./ha (soybean) for terrestrial habitats.

Currently, the buffer zones determined for ground applications are based on a standard set of assumptions for spray configuration and weather conditions, yet many variable conditions exist at any spray site. To allow for increased flexibility, the PMRA has developed a proposal with the provinces, which will allow the applicator to factor in the actual values for spray characteristics, wind speed and to some extent, the sensitivity of the habitat to be protected. There would also be the possibility of factoring in advances in spray application technology which can reduce spray drift (e.g. low drift nozzles, shrouds, cones). Consequently, individual applicators could reduce the size of the spray buffer zone if they employ some of these measures to protect the habitat in question. With the use of shrouds and cones on spray booms, it has been estimated that the buffer zones can be reduced by 70% and 30%, respectively. For more information on the proposal, please consult PRO2005-06, *Agricultural Buffer Zone Strategy Proposal.*

Aerial buffer zones were calculated using the AgDisp model. Similar to the ground buffer zones, the aerial buffer zones were based on the maximum application rates and the most sensitive aquatic (*Selenastrum capricornutum*: NOEC = 0.0049 mg a.i./L) and terrestrial (soybean: EC_{25} = 3 g a.i./ha) species. The calculated ground and aerial buffer zones are presented in Section 8.2.4.

6.0 Use of Dicamba and Its Alternatives

Data regarding the use of dicamba were consulted during the health and environmental assessments. As the use of dicamba to control woody plants in industrial (non-crop) sites raised some concerns regarding occupational exposure that required mitigation, further analysis of that use of dicamba was conducted.

6.1 Commercial and/or Restricted Class Products

Appendix VII lists the use information considered in the PMRA's risk assessments for the supported use that has risk concerns. This information includes maximum single application rate of active ingredient applied to the site, the maximum cumulative rate of active ingredient applied to the site per year, maximum number of applications to the specific site per year and the minimum number of days between applications.

6.2 Alternatives to Dicamba Use

The registered chemical alternatives for the supported use of dicamba that has risk concerns, are listed in Appendix VIII. While the chemical control methods are registered, the PMRA has not commented on the availability and extent of use of these options.

Most sources of non-chemical alternatives are focussed on general agronomic practices. The PMRA searched information available for specific site-pest combinations and found a couple of non-chemical measures of pest control. The effectiveness and extent of use of these non-chemical control measures are not verified. For the control of broadleaf weeds and brush in non-crop areas, these measures are:

- mowing weeds and brush, and
- using mulch or geotextiles around buildings or facilities.

The PMRA welcomes feedback on the availability and extent of use of the chemical alternatives to dicamba in Appendix VIII and further information regarding the availability, effectiveness and extent of use of non-chemical control methods.

6.3 Domestic Class Products

Domestic class products containing dicamba are used only on fine turf and were reviewed separately, in PACR 2007-02.

7.0 Other Assessment Considerations

7.1 Toxic Substances Management Policy

During the review of dicamba, the PMRA has taken into account the federal Toxic Substances Management Policy (TSMP)[2] and has followed its Regulatory Directive DIR99-03[3]. It has been determined that this active and one of its major transformation products do not meet the criteria TSMP Track 1 substances for the following reasons.

- Dicamba is not bioaccumulative. The log *n*-octanol–water partition coefficient (log K_{ow}) is 0.1, which is below the TSMP Track 1 cut-off criterion of log K_{ow} 5.0.
- Dicamba does not meet the criteria for persistence because its half-life values in water (up to 55.9 days), and soil (up to 31.3 days) are below the TSMP Track 1 cut-off criteria for water (182 days), sediment (182 days) and soil (182 days). No data were provided for persistence of dicamba in air.
- As described in Sections 4 and 5.2, dicamba does not meet the TSMP criteria for toxicity.
- The major transformation product 3,6-DCSA does not meet the TSMP Track 1 cut-off criterion for bioaccumulation (log $K_{ow} > 5.0$). The log K_{ow} of 3,6-DCSA is 0.24. No data were available on the persistence of 3,6-DCSA in soil, water and air or on its toxicity.

Technical grade products containing dicamba could contain polychlorinated-*p*-dibenzodioxins and polychlorinated dibenzofurans substituted in at least the 2,3,7,8-positions at levels of less than 1 ppb. The end-use products containing the active ingredient would contain even lower levels, depending on the amount of the technical grade active ingredient used in the formulation. Subsequent use of formulated products could lead to environmental releases of these microcontaminants that would be close to environmental background levels. As noted in Health

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2 The federal Toxic Substances Management Policy is available through Environment Canada's website at www.ec.gc.ca/toxics.

3 Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, is available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca; or through our website at www.pmra-arla.gc.ca.

Canada's *It's Your Health* publication, the greatest sources of dioxins in the environment include the incineration of medical and municipal waste, the burning of fuel and wood, electrical power generation and tobacco smoke. More information on sources of dioxins in Canada may be found at www.hc-sc.gc.ca/iyh-vsv/environ/dioxin_e.html.

As 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (2,3,7,8-TCDD) and other dioxins of concern are Track 1 substances under the *Canadian Environmental Protection Act* and subject to virtual elimination under PMRA's Toxic Substance Management Policy, the PMRA will continue to monitor dioxin levels in dicamba by requesting and reviewing data produced using the most sensitive and readily available analytical methods.

7.2 Formulant Issues

Products containing dicamba are subject to all the requirements of Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*, published on 31 May 2006.

Based on the considerations outlined in Section 4.1, Toxicology Summary, the PMRA is proposing that the DEA form of dicamba be phased out (see Section 8.1).

DMA formulations may contain trace levels of N-nitrosodimethylamine (NDMA). Typically, NDMA, if present as a microcontaminant, is at a concentration of less than 1 ppm. Toxicology studies done with these pesticide formulations do not exhibit any of the toxicological findings that are characteristic of NDMA. Also, NDMA is rapidly decomposed by sunlight; therefore, it does not persist in the environment under use conditions. Thus, it is unlikely that trace levels of NDMA from pesticide sources would pose a health risk to humans. However, the PMRA will monitor the level of NDMA in certain formulations by requiring registrants to specify NDMA levels in the DMA used for manufacturing purposes (see Section 9.1.1).

8.0 Proposed Regulatory Action

The use of dicamba on agricultural and industrial site is acceptable for continuing registration provided that the mitigation measures described in Section 8.1 are implemented. Standard label precautionary statements and improvements are also recommended in Section 8.2 to further protect workers and the environment.

8.1 Mitigation Measures

8.1.1 Phase-out of Products Containing the DEA Form

There was no toxicological information on the DEA form of dicamba. In light of published studies on toxicological effects of DEA and in the absence of a toxicological and exposure database with which to conduct a quantitative risk assessment, the PMRA is proposing that dicamba formulations containing DEA be phased out.

8.1.2 New Maximum Application Rate for Some Uses

The PMRA has determined that the worker application and postapplication risks are acceptable for short-term exposure scenarios. For intermediate-term exposure scenarios (non-cropland uses), the calculated MOEs are less than the target MOEs in the high-pressure handwand scenario. To reach target MOEs, the maximum application rate for a maximum spray liquid concentration of 0.01 kg a.e./L for non-cropland uses with high-volume handwand applications needs to be established.

8.1.3 New Buffer Zones

Buffer zones are required to protect terrestrial habitat, as shown in Section 8.2.4.

8.2 Label Recommendations and Improvements

8.2.1 General

The statement "Keep out of reach of children" must appear on the primary panel of all labels of products available for homeowner use.

8.2.2 Label Statements Relating to the Guarantee

The guarantee statement on the labels of all products should be revised, when necessary, to specify the form of dicamba contained (i.e. one of the forms indicated in Section 2.3, Table 2.3.1) and the percentage of dicamba acid equivalents. For example, for the DMA form, the guarantee should read: "Dicamba, present as the dimethylamine salt... y%" for solid products or "y g/L" for liquid products where "y" is the equivalent concentration of dicamba as the acid.

8.2.3 Label Statements Relating to Human Health

The labels of technical, manufacturing and commercial class products containing dicamba must include the following text:

> **Toxicological information**
>
> Dicamba may cause severe irritation to the eyes, and irritation to the skin, and mucous membranes. Symptoms of overexposure to dicamba may include dizziness, muscle weakness, loss of appetite, weight loss, vomiting, decreased heart rate, shortness of breath, excitement, tenseness, depression, incontinence, cyanosis, muscle spasms, exhaustion, loss of voice. Treat symptomatically.

8.2.3.1 Proposed Label Statements Relating to Mixer/Loader/Applicator and Postapplication Exposure

For barley, lowbush blueberries, canary grass, corn (field and sweet), fallow, oats, pastures, red fescue, spring rye, seedling grasses, stubble fields, summer fallow and wheat (spring, durum), the following label statements are required:

> Applicators must wear a long-sleeved shirt, long pants and chemical-resistant gloves.
>
> Do not re-enter treated fields for 12 hours.

For non-crop areas (roadsides, hydro, pipeline and railway rights-of-way, airports, military bases, turf, wasteland), the following label statements are required:

> Applicators must wear coveralls over long pants and a long-sleeved shirt, and chemical-resistant gloves.
>
> For high-volume handwand applications, applicators must wear chemical-resistant coveralls over long pants and a long-sleeved shirt, chemical-resistant gloves and a respirator. Apply at a maximum spray liquid concentration of 0.01 kg a.e./L or use a minimum spray volume of 500 L/hectare.

For non-cropland aerial application, the following label statements are required:

> Aerial applicators must wear a long pants and a long-sleeved shirt.
>
> Aerial mixers/loaders must wear long pants and a long-sleeved shirt and chemical-resistant gloves.
>
> Must use closed cab aircraft.
>
> Mixer/loader and applicator must be different individuals.
>
> No human flaggers are permitted.

8.2.3.2 Label Statements Relating to the Dietary Risk Assessment

As required by Regulatory Directive DIR93-18, *Pre-harvest Intervals for Grazing and Cutting for Hay of Immature Crops Treated with Pesticides*, labels should not be silent with respect to preharvest intervals prior to grazing, feeding to livestock and harvesting for hay. In the case of dicamba, insufficient data are available to establish the appropriate intervals. However, instead of leaving the labels silent, the grazing restrictions recommended by in Note to CAPCO C94-08, *2,4-D Re-evaluation Update and Label Improvement Program*, are proposed in the interim.

For barley, oats, spring rye, wheat, field corn, stubble land, pastures, rangelands, road sides and uncropped land, the following statements are required:

> Do not permit lactating dairy animals to graze fields within 7 days after application.
>
> Do not harvest forage or cut hay within 30 days after application.
>
> Withdraw meat animals from treated fields at least 3 days before slaughter.

8.2.4 Label Statements Relating to the Environment

In addition to those that already exist on the label, the following label statements must be included under **ENVIRONMENTAL HAZARDS**:

> TOXIC to aquatic organisms and non-target terrestrial plants.

In addition to those that already exist on the label, the following label statements must be included under **DIRECTIONS FOR USE**:

> DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats.
>
> DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.
>
> To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil or clay. Avoid application when heavy rain is forecast. Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.
>
> To minimize possible contamination of groundwater, the use of spot treatment applications is recommended in areas where soils are permeable (e.g. sandy soil) or the water table is shallow.
>
> Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification.
>
> Aerial application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply when wind speed is greater than 16 km/h at flying height at the site of application. DO NOT apply with spray droplets smaller than the American Society of Agricultural

Engineers (ASAE) medium classification. DO NOT allow nozzle spacing to exceed 65% of boom length.

For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies which minimize off-site drift, including meteorological conditions (e.g. wind direction, low wind speed) and spray equipment (e.g. coarse droplet sizes, minimizing height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.

BUFFER ZONES

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, pastures, rangelands, and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/ marine habitats.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone recommended of the products involved in the tank mixture.

Method of application	Crop / Use	Buffer Zones (metres) Required for the Protection of:						
		Freshwater Habitat of Depths			Estuarine/Marine Habitats of Depths			Terrestrial Habitat
		Less than 1 m	1 to 3 m	Greater than 3 m	Less than 1 m	1 to 3 m	Greater than 3 m	
Field sprayer[a]	Barley, oats, spring rye, wheat, canary grass, forage grass seedlings	0	0	0	0	0	0	2
	Corn, red fescue, established forage grass	1	1	0	1	0	0	5
	Blueberries (lowbush)	4	3	1	2	2	1	30
	Non-crop land and industrial sites	4	4	2	2	2	1	35
	Rights-of-way, roadsides, utility lines	4	4	2	2	2	1	Not required
	Stubble fields/ fallow land	2	1	1	1	1	0	10
	Pasture, rangeland	3	2	1	1	1	0	20

Method of application	Crop / Use		Buffer Zones (metres) Required for the Protection of:						
			Freshwater Habitat of Depths			Estuarine/Marine Habitats of Depths			Terrestrial Habitat
			Less than 1 m	1 to 3 m	Greater than 3 m	Less than 1 m	1 to 3 m	Greater than 3 m	
Aerial	Barley, oats, spring rye, wheat	Fixed-wing	2	0	0	0	0	0	75
		Rotary-wing	0	0	0	0	0	0	60
	Canary grass	Fixed-wing	0	0	0	0	0	0	65
		Rotary-wing	0	0	0	0	0	0	50
	Stubble fields/ fallow	Fixed-wing	1	0	0	0	0	0	80
		Rotary-wing	0	0	0	0	0	0	65
	Non-crop land	Fixed-wing	450	375	150	225	200	70	800
		Rotary-wing	200	150	60	90	75	35	800
	Rights-of-way, roadsides, utility lines	Fixed-wing	450	400	175	250	225	100	Not required
		Rotary-wing	300	225	100	150	125	70	Not required
	Industrial sites	Fixed-wing	450	400	175	250	225	100	800
		Rotary-wing	300	225	100	150	125	70	800

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

DISPOSAL

Disposal statements should be in compliance with Regulatory Directive DIR99-04, *Disposal Statements for Control Product Labels*.

8.2.5 Label Changes Relating to Value

Replace the designation "Canary grass" with "Canary seed" (*Phalaris canariensis*). "Canary grass" can be easily mistaken as "Reed canary grass" (*Phalaris arundinacea)*. This is required for the labels of pest control products with Registration Numbers 13761, 18837, 23957, 24362, 25583, 25605 and 26722.

For the label of the pest control product with Registration Number 26980, the statement "Do not apply by air." must be added under the following sections:

- "Stem foliage" in the section "Brush control"
- "Broadleaf weed control"
- "Roadside vegetation control"

To all labels, the statement "apply once per season per use site" must be added with the following exceptions:

- For the products used on field corn with the Registration Numbers 18837, 23957, 24362, 26722, the following statement is required:

  > Apply once per season per use site. For the sequential postemergent application in field corn, 2 applications may be applied 14 days apart.

- For the products used for Jerusalem artichoke control with Registration Numbers 9606, 27856, 8885, the following statement is required:

  > Apply once per season per use site. For the Jerusalem Artichoke control in corn, 2 applications may be applied 10–14 days apart.

- For Vanquish, Registration Number 26980, the following statement is required:

  > Typically, apply once per season per use site. If weed regrowth occurs, a second application may be applied 7–10 days after the first application.

8.3 Residue Definition

Based on the available metabolism data, the proposed residue definition in plants and animals is the parent compound dicamba and metabolites 5-hydroxydicamba and 3,6-DCSA. 3,6-DCSA is included for plants and commodities based on the American decision to regulate residues of 3,6-DCSA on soybean and asparagus.

The dicamba isomer 3,5-dichloro-2-methoxybenzoic acid is present in at least one of the technical products at significant concentrations according to the available product chemistry data. As this isomer is considered to have activity similar to dicamba, it is proposed that this compound be included in the residue definition unless there is sufficient evidence to demonstrate 3,5-dichloro-2-methoxybenzoic acid is not present in the technical or related end-use products at significant concentrations.

The residue definition is tentative pending the receipt of additional metabolism and magnitude-of-residue data for the registered food uses.

8.4 Maximum Residue Limits of Dicamba in Food

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to update Canadian maximum residue limits (MRLs) and to remove MRLs that are no longer supported. The Agency recognizes, however, that interested parties may want to retain an MRL in the absence of a Canadian registration to allow legal importation of treated commodities into Canada. The PMRA requires similar chemistry and toxicology data for such import MRLs as those required to support Canadian food use registrations. In addition, the PMRA requires residue data that are representative of use conditions in exporting countries, in the same manner

that representative residue data are required to support domestic use of the pesticide. These requirements are necessary so that the Agency may determine whether the requested MRLs are needed, and to ensure they would not result in unacceptable health risks.

Division 15, Table II, of the Food and Drug Regulations currently provides no residue definition and no MRLs are specified. The supported food uses of dicamba are barley, blueberry (postharvest use on lowbush variety only), corn, oats, spring rye and wheat. As dicamba is also registered for use on animal feed and forage crops, secondary residues of dicamba that may be transferred to animal commodities such as meat and milk are subject to regulation.

Residues in all agricultural commodities, including those approved for treatment in Canada but without a specified MRL (i.e. grain crops, beef and milk), must not exceed 0.1 ppm, a general MRL specified in subsection B.15.002(1) of the Food and Drug Regulations. Changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*.

The general MRL of 0.1 ppm will apply for enforcement purposes with respect to the residues of dicamba in food for all commodities, including registered label uses. Parties interested in supporting an import MRL for residues of dicamba on other commodities should contact the PMRA during the comment period of this document to discuss the submission of appropriate data.

9.0 Additional Data Requirements

The following data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient are required to provide these data or an acceptable scientific rationale within the timeline specified in a decision letter that will be sent to the registrants when a final re-evaluation decision is made.

9.1 Data Requirements Relating to Chemistry

9.1.1 All Products to which DMA Is Added During the Manufacturing/Formulation Process

- Updated Statement Product Specification Forms identifying the levels of NDMA present in the DMA that is added. This requirement pertains only to products where DMA is added as part of the manufacturing/formulating process; it does not apply to products that use the already manufactured DMA form of dicamba in the formulation process.

9.1.2 Data on Microcontaminants

- Analysis of the most recent five batches of each technical product for microcontaminants of concern, using the most sensitive appropriate analytical methods for 2,3,7,8-TCDD, 2,3,7,8-tetrachlorodibenzofuran (2,3,7,8-TCDF) and their respective higher substituted chlorinated congeners.

9.2 Data Requirements Related to Toxicology

- Acute inhalation study (data code [DACO] 4.2.3); the available study is inadequate in that it does not give reliable accounts of achieved dosages

- Combined chronic/carcinogenicity study in rats (DACO 4.4.4); the available rat study was conducted below the maximum tolerated dose with no effects elicited at the high dose

9.3 Data requirements Related to Occupational Exposure

Sufficient data are available to assess the occupational exposure risks from the existing use pattern, however additional data may be required to support any expansion of use.

9.4 Data Requirements Related to Dietary Exposure

Sufficient data are available to assess the dietary risks from the existing use patterns, however additional data may be required to support any expansion of use.

9.5 Additional Data Requirements Relating to Environmental Risks

To assess the impact of 3,6-DCSA on the environment, the following studies with 3,6-DCSA:

- Aerobic water/sediment biotransformation (DACO 8.2.3.5.4)
- Acute aquatic invertebrate toxicity (DACO 9.3.2)
- Acute fish toxicity (DACO 9.5.2.1, 9.5.2.2)

10.0 Proposed Re-evaluation Decision

The PMRA has carried out an assessment of available information on agricultural and industrial uses of dicamba in addition to the previous review of lawn and turf uses (PACR2007-02) and is proposing that dicamba and all associated end-use products are acceptable for continued registration as described.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed decision.

List of Abbreviations

µg	microgram(s)
°C	degree(s) Celcius
2,3,7,8-TCDD	2,3,7,8-tetrachlorodibenzo-*p*-dioxin
2,3,7,8-TCDF	2,3,7,8-tetrechlorodibenzofuran
3,6-DCSA	3,6-dichlorosalicylic acid
a.i.	active ingredient
a.e.	acid equivalent
ADI	acceptable daily intake
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
atm	atmosphere(s)
bw	body weight
DACO	data code
DEA	diethanolamine salt
DEEM	Dietary Exposure Evaluation Model
DGA	diglycolamine
DMA	dimethylamine salt
DT_{50}	time required for 50% dissipation
DT_{90}	time required for 90% dissipation
DWLOC	drinking water level of comparison
EC_{25}	effect concentration 25%
EEC	expected environmental concentration
EXAMS	Exposure Analysis Modeling System
F_1	first filial generation
g	gram(s)
ha	hectare(s)
Hg	mercury
IPA	isoproponylamine
K	potassium
kg	kilogram(s)
K_{oc}	adsorption coefficient normalized for organic carbon
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
m	metre(s)
m^3	cubic metre(s)
mg	milligram(s)
mm	millimetre(s)
MOE	margin of exposure
mol	mole(s)
mPa	millipascal(s)
MRL	maximum residue limit
Na	sodium

ng	nanogram(s)
nm	nanometre(s)
NDMA	N-nitrosodimethylamine
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
Pa	Pascal
PACR	Proposed Acceptability for Continuing Registration
PHED	Pesticide Handlers Exposure Database
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppm	parts per million
PRZM	Pesticide Root Zone Model
RQ	risk quotient
SF	safety factor
$t_{1/2}$	half-life
TSMP	Toxic Substances Management Policy
UF	uncertainty factor
UV	ultraviolet

Appendix I Dicamba Products Currently Registered (excluding discontinued products, products with a submission for discontinuation or products registered for use on fine turf only) as of 7 March 2005

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee	Form of Dicamba
19290	Technical	BASF Canada Inc.	Banvel Dicamba Technical Herbicide	Solid	86.1%	Acid
26613	Technical	Syngenta Crop Protection Canada Inc.	Syngenta Dicamba Technical Herbicide	Solid	86.1%	Acid
26718	Technical	Gharda USA, Inc.	Gharda Dicamba Technical Herbicide	Solid	98.3%	Acid
20354	Manufacturing Concentrate	BASF Canada Inc.	Banvel K Dicamba K Manufacturing Concentrate	Solution	43.03%	K
27991	Manufacturing Concentrate	PBI/Gordon Corp.	Trimec DMB #2 Herbicide Powder	Dust or powder	4.40%	Acid
25774	Manufacturing Concentrate	Syngenta Crop Protection Canada Inc.	Dicamba 480 Manufacturing Concentrate	Solution	480 g/L	DMA
25876	Manufacturing Concentrate	BASF Canada Inc.	Banvel 480 Manufacturing Concentrate	Solution	480 g/L	DMA
26143	Manufacturing Concentrate	BASF Canada Inc.	Distinct Herbicide Manufacturing Concentrate	Wettable granules	50.0%	Na
26721	Manufacturing Concentrate	Gharda USA, Inc.	Gharda Dicamba Manufacturing Concentrate Herbicide	Solution	480 g/L	DMA
27721	Manufacturing Concentrate	Scotts Canada Ltd.	Killex 3X Manufacturing Concentrate II (Green Cross)	Solution	27 g/L	DMA
8885	Commercial	Syngenta Crop Protection Canada Inc.	Target DS Liquid Herbicide	Solution	110 g/L	Amine
9606	Commercial	BASF Canada Inc.	Dyvel DS Liquid Herbicide	Solution	110 g/L	DMA
11547	Commercial	Syngenta Crop Protection Canada Inc.	Dycleer 24 Liquid Herbicide	Solution	200 g/L	DMA
13761	Commercial	Syngenta Crop Protection Canada Inc.	Target Liquid Systemic Herbicide	Solution	62.5 g/L	Amine
16545	Commercial	BASF Canada Inc.	Dyvel Herbicide (Agricultural)	Solution	84 g/L	DMA
18837	Commercial	BASF Canada Inc.	Banvel Herbicide	Solution	483 g/L	DMA
19349	Commercial	BASF Canada Inc.	Marksman Herbicide (Agricultural)	Suspension	132 g/L	K
20423	Commercial	Monsanto Canada Inc.	Mocan 943 Water Soluble Herbicide	Solution	86 g/L	IPA
21572	Commercial	Monsanto Canada Inc.	Rustler Liquid Herbicide	Solution	60 g/L	IPA
23957	Commercial	BASF Canada Inc.	Banvel II Herbicide Agricultural	Solution	480 g/L	DGA
24362	Commercial	BASF Canada Inc.	Banvel Dry Herbicide Agricultural	Wettable granules	70%	Na

Appendix I Dicamba Products Currently Registered (excluding discontinued products, products with a submission for discontinuation or products registered for use on fine turf only) as of 7 March 2005

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee	Form of Dicamba[1]
19290	Technical	BASF Canada Inc.	Banvel Dicamba Technical Herbicide	Solid	86.1%	Acid
26613	Technical	Syngenta Crop Protection Canada Inc.	Syngenta Dicamba Technical Herbicide	Solid	86.1%	Acid
26718	Technical	Gharda USA, Inc.	Gharda Dicamba Technical Herbicide	Solid	98.3%	Acid
20354	Manufacturing Concentrate	BASF Canada Inc.	Banvel K Dicamba K Manufacturing Concentrate	Solution	43.03%	K
27991	Manufacturing Concentrate	PBI/Gordon Corp.	Trimec DMB #2 Herbicide Powder	Dust or powder	4.40%	Acid
25774	Manufacturing Concentrate	Syngenta Crop Protection Canada Inc.	Dicamba 480 Manufacturing Concentrate	Solution	480 g/L	DMA
25876	Manufacturing Concentrate	BASF Canada Inc.	Banvel 480 Manufacturing Concentrate	Solution	480 g/L	DMA
26143	Manufacturing Concentrate	BASF Canada Inc.	Distinct Herbicide Manufacturing Concentrate	Wettable granules	50.0%	Na
26721	Manufacturing Concentrate	Gharda USA, Inc.	Gharda Dicamba Manufacturing Concentrate Herbicide	Solution	480 g/L	DMA
27721	Manufacturing Concentrate	Scotts Canada Ltd.	Killex 3X Manufacturing Concentrate II (Green Cross)	Solution	27 g/L	DMA
8885	Commercial	Syngenta Crop Protection Canada Inc.	Target DS Liquid Herbicide	Solution	110 g/L	Amine
9606	Commercial	BASF Canada Inc.	Dyvel DS Liquid Herbicide	Solution	110 g/L	DMA
11547	Commercial	Syngenta Crop Protection Canada Inc.	Dycleer 24 Liquid Herbicide	Solution	200 g/L	DMA
13761	Commercial	Syngenta Crop Protection Canada Inc.	Target Liquid Systemic Herbicide	Solution	62.5 g/L	Amine
16545	Commercial	BASF Canada Inc.	Dyvel Herbicide (Agricultural)	Solution	84 g/L	DMA
18837	Commercial	BASF Canada Inc.	Banvel Herbicide	Solution	483 g/L	DMA
19349	Commercial	BASF Canada Inc.	Marksman Herbicide (Agricultural)	Suspension	132 g/L	K
20423	Commercial	Monsanto Canada Inc.	Mocan 943 Water Soluble Herbicide	Solution	86 g/L	IPA
21572	Commercial	Monsanto Canada Inc.	Rustler Liquid Herbicide	Solution	60 g/L	IPA
23957	Commercial	BASF Canada Inc.	Banvel II Herbicide Agricultural	Solution	480 g/L	DGA
24362	Commercial	BASF Canada Inc.	Banvel Dry Herbicide Agricultural	Wettable granules	70%	Na

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee	Form of Dicamba[1]
24754	Commercial	Syngenta Crop Protection Canada Inc.	Pal Herbicide (a component of county tank mix)	Solution	84 g/L	DMA
25583	Commercial	United Agri ProductsCanada Inc.	Sword Herbicide	Solution	62.5 g/L	Amine
25605	Commercial	Interprovincial Cooperative Limited	IPCO Tracker Liquid Herbicide	Solution	62.5 g/L	Amine
25811	Commercial	BASF Canada Inc.	Distinct Herbicide	Wettable granules	50%	Na
26406	Commercial	BASF Canada Inc.	Distinct WDG Herbicide	Wettable granules	50%	Na
26688	Commercial	Syngenta Crop Protection Canada Inc.	Summit WG Herbicide	Wettable granules	39.9%	Na
26722	Commercial	Gharda USA, Inc.	Oracle Dicamba Agricultural Herbicide	Solution	480 g/L	DMA
26980	Commercial	Syngenta Crop Protection Canada Inc.	Vanquish Herbicide	Solution	480 g/L	DGA
27200	Commercial	Monsanto Canada Inc.	Rustler Liquid Herbicide	Solution	46 g/L	IPA
27856	Commercial	BASF Canada Inc.	Dyvel DSP Liquid Herbicide	Solution	110 g/L	DMA

[1] According to primary panel of label.

DEA = diethanolamine, DGA = diglycolamine, DMA = dimethylamine, IPA = isoproponylamine , K = potassium salt, Na = sodium salt, Amine = DEA or DMA.

Appendix II Registered Canadian Uses (excluding use on fine turf) of Dicamba as of 1 February 2005

Site(s)	Pests(s)	Marketing Class	Formulation Type	Application Methods and Equipment
Use-Site Category 13—Terrestrial Feed Crops				
Canary seed	Broadleaf weeds	Commercial	Wettable granules, solution	Ground (boom) or air
Grasses (forage, seed production)	Broadleaf weeds	Commercial	Wettable granules, solution	Ground (boom)
Pastures/Rangeland	Broadleaf weeds and brush	Commercial	Wettable granules, solution	Ground (boom), handwand sprayer, backpack
Stubble and summer fallow fields	Broadleaf weeds	Commercial	Wettable granules, solution	Ground (boom) or air
Use-Site Category 14—Terrestrial Food Crops				
Corn (Sweet)	Broadleaf weeds	Commercial	Solution	Ground (boom)
Blueberries (lowbush)	Broadleaf weeds	Commercial	Solution	Ground (boom)
Use-Site Category 13—Terrestrial Feed Crops Use-Site Category 14—Terrestrial Food Crops				
Barley, Oats, Wheat (spring, durum, winter), Spring rye (spring)	Broadleaf weeds	Commercial	Wettable granules, solution	Ground (boom) or air
Corn (Field)	Broadleaf weeds	Commercial	Wettable granules, solution, suspension	Ground (boom)
Use-Site Category 16—Industrial and Domestic Vegetation Control Non-Food Sites				
Non-crop areas	Broadleaf weeds and brush	Commercial	Wettable granules, solution	Ground (boom), handwand sprayer, backpack or air

All uses are supported by the registrant.

Appendix III Toxicology Endpoints for Risk Assessment for Dicamba

Exposure Scenario	Dose (mg/kg bw/day)	Endpoint	Study	UF/SF or MOE
Acute Dietary	NOAEL = 30	Clinical signs (ataxia)	Developmental – Rabbit	100
	ARfD = 0.3 mg/kg bw			
Chronic Dietary	NOAEL = 11.2	Alterations in clinical chemistry and inflammation of the prostate	1-Year Oral Toxicity – Dog	1000
	ADI = 0.011 mg/kg bw/day			
Short-Term[a] Dermal	Dermal NOAEL = 1000	Increased blood glucose; and decreased body weight, urine pH, hemoglobin and total protein	21-Day Dermal Toxicity – Rabbit	300
Intermediate-Term[b] Dermal	Dermal NOAEL = 1000	Increased blood glucose; and decreased body weight, urine pH, hemoglobin and total protein	21-Day Dermal Toxicity – Rabbit	1000
Short-Term[a] Inhalation[c]	Oral NOAEL = 30	Clinical signs (ataxia)	Developmental – Rabbit	300
Intermediate-Term[b] Inhalation[c]	Oral NOAEL = 11.2	Alterations in clinical chemistry and inflammation of the prostate	1-Year Oral Toxicity – Dog	300

[a] Duration of exposure is defined as 1 day to 6 weeks

[b] Duration of exposure is 6 to 12 weeks.

[c] As an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) should be used in route-to-route extrapolation.

Appendix IV Mixer/Loader/Applicator Short-Term Exposure Estimates and MOEs with Baseline[a] PPE

Crop	Method of Application[a]	Formulation	Rate[b] kg a.e./ha	Area Treated[c] ha/day	Daily Exposure µg/kg/day		Margins of Exposure	
					Dermal[d]	Inhalation[e]	Dermal[f]	Inhalation[g]
Barley, oats, spring rye and wheat (spring, winter, durum)	Groundboom	Solution	0.152	300	54.48	1.668	18356	17 989
				100	18.16	0.556	55067	53 968
	Aerial (mixer/ loader)	Solution	0.14	400	40.91	1.28	24443	23 438
	Aerial (applicator)	Solution	0.14	400	7.728	0.056	129 400	535 714
Oats, spring rye, wheat (spring and winter)	Groundboom	Wettable granules	0.14	300	117.8	1.188	8492	25 253
				100	39.25	0.396	25 476	75 758
	Aerial (mixer/ loader)	Wettable granules	0.14	400	131.02	0.816	7633	36 765
	Aerial (applicator)	Wettable granules	0.14	400	7.728	0.056	129 400	535 714
Barley (spring)	Groundboom	Wettable granules	0.112	300	94.2	0.95	10 615	31 566
				100	31.4	0.3168	31 846	94 697
	Aerial (mixer/ loader)	Wettable granules	0.112	400	104.81	0.6528	9541	45 956
	Aerial (applicator)	Wettable granules	0.112	400	6.182	0.6528	161 749	45 956
Corn (field)	Groundboom	Solution	0.604	300	216.48	6.627	4619	4527
				100	72.16	2.209	13 858	13 581
		Wettable granules	0.602	300	506.4	5.108	1975	5873
				100	168.78	1.7028	5925	17 618
Corn (sweet)	Groundboom	Solution	0.121	300	43.37	1.328	23 058	22 598
				100	14.46	0.443	69 175	67 794
Fallow land (including summerfallow)	Groundboom	Solution	1.208	300	432.96	13.253	2310	2264
				100	144.32	4.418	6929	6791
	Aerial (mixer/ loader)	Solution	0.125	400	36.529	1.143	27 376	26 250
	Aerial (applicator)				6.9	0.05	144928	600 000
	Groundboom	Wettable granules	1.19	300	1000.93	10.098	999	2971
				100	333.64	3.366	2997	8913
Red fescue	Groundboom	Solution	0.29	300	103.9	3.182	9621	9429
				100	34.65	1.061	28 863	28 287
		Wettable granules	0.287	300	241.4	2.435	4143	12 318
				100	80.47	0.812	12 428	36 955

Crop	Method of Application[a]	Formulation	Rate[b] kg a.e./ha	Area Treated[c] ha/day	Daily Exposure µg/kg/day		Margins of Exposure	
					Dermal[d]	Inhalation[e]	Dermal[f]	Inhalation[g]
Forage grasses—seedlings	Groundboom	Solution	0.14	300	50.18	1.536	19 929	19 531
				100	16.73	0.512	59 787	58 594
Forage grasses—established			0.29	300	103.9	3.182	9621	9429
				100	34.65	1.061	28 863	28 287
Stubble fields	Groundboom	Solution	1.208	300	433	13.25	2310	2264
				100	144.32	4.418	6929	6791
		Wettable granules	1.19	300	1000.93	10.098	999	2971
				100	333.64	3.366	2997	8913
	Aerial (mixer/loader)	Solution	0.1250	400	36.529	1.143	27 376	26 250
	Aerial (applicator)	Solution		400	6.9	0.05	14 4928	600 000
Pasture and rangeland	Groundboom	Solution	2.222	300	796.4	24.379	1256	1231
				100	265.47	8.126	3767	3692
		Wettable granules	2.24	300	1884	19.01	531	1578
				100	628.03	6.336	1592	4735
Canary grass	Groundboom	Solution	0.14	300	50.18	1.536	19 929	19 531
				100	16.73	0.512	59 787	58 594
	Aerial (mixer/loader)		0.094	400	27.411	0.8576	36 482	34 981
	Aerial (applicator)				5.178	0.0375	193 134	799 574
	Groundboom	Wettable granules	0.14	300	117.8	1.188	8492	25 253
				100	39.25	0.396	25 476	75 758
Lowbush blueberry	Groundboom	Solution	3.429	30	122.9	2.56	8137	7974
	Backpack	Solution	0.0062[h]	150[h]	72.35	0.825	13 821	36 362
	Low-pressure handwand	Solution	0.0062[h]	150[h]	12.53	0.6005	79 787	49 957

[a] Baseline PPE: single layer (long pants and long-sleeved shirt) and chemical-resistant gloves.
[b] Maximum label rate.
[c] Based on default assumptions and crop specific data—these values are considered conservative estimates and could be further refined.
[d] Where dermal exposure µg/kg/day = (unit exposure × area treated × rate) / 70 kg bw.
[e] Where inhalation exposure µg/kg/day = (unit exposure × area treated × rate) / 70 kg bw.
[f] Based on a dermal NOAEL of 1000 mg/kg bw/day (target MOE of 300) for short-term exposure scenarios.
[g] Based on an inhalation NOAEL of 30 mg/kg bw/day (target MOE of 300) for short-term exposure scenarios.
[h] Application rate expressed as kg a.e./L.
[i] Area treated expressed as L/day.

Appendix V Intermediate-Term Exposure Estimates and MOEs with Mid-Level PPE

Crop	Method of Application	Formulation	Rate (kg a.e./L)	Area Treated (L/day)	Daily Exposure (µg/kg/day)		MOE (Uncertainty Factor)		
					Dermal	Inhalation	Dermal	Inhalation	Inhalation
Non-cropland (brush control)	Aerial (mixer/loader)	Solution	2.016	490	721.69	22.579	1386	496	4960
	Aerial (applicator)	Solution	2.016	490	136.32	0.9878	7336	11338	NA
	Right-of-way	Solution	2.496	18	357.4	4.236	2798	2644	26 440
	Backpack	Solution	0.0025[h]	150[i]	13.913	0.3327	71 875	33 666	336 661
	Low-pressure handwand	Solution	0.0025[h]	150[i]	3.939	0.2421	253 892	46 254	462 537
	High-pressure handwand	Solution	0.0025[h]	3750[i]	328.596	20.223	3043	554	5538
Non-cropland (broadleaf control)	Right-of-way	Solution	4.416	18	632.32	7.495	1581	1494	14 944
	Right-of-way	Wettable granules	2.242.24	1818	354.82	3.468	2818	3230	32 300
	Backpack	Solution	0.0401[h]	150[i]	223.164	5.336	4481	2099	20 989
		Wettable granules	0.0204[h]	150[i]	117.55	2.759	8507	4059	40 591
	Low-pressure handwand	Solution	0.0401[h]	150[i]	63.176	3.884	15 829	2884	28 836
		Wettable granules	0.0204[h]	150[i]	36.159	2.02	27 656	5543	55 433
	High-pressure handwand	Solution	0.0401[h]	3750[i]	5270.7	324.38	[illegible]	[illegible]	345
			0.01[h]	3750[i]	1314.4	80.89	[illegible]	[illegible]	1385
		Wettable granules	0.0204[h]	3750[i]	2781.82	166.14	[illegible]	[illegible]	674
			0.01[h]	3750[i]	1363.64	81.439	[illegible]	[illegible]	1375

a Mid-level PPE: Coveralls and gloves over a single layer (long pants and long-sleeved shirt), except aerial applicator and mixer/loader—only single layer and gloves.
b Rate for high-pressure handwand based on volume of 110 L/ha for broadleaf control and 220 L/ha for brush control; lower rate based on 440 L/ha for broadleaf control (solution), 220 L/ha for wettable granule and 250 L/ha for brush control (solution).
c Where dermal exposureµg/kg/day = (unit exposure × area treated × rate) / 70 kg bw.
d Where inhalation exposureµg/kg/day = (unit exposure × area treated × rate)/70 kg bw (no respirator).
e Based on a dermal NOAEL of 1000 mg/kg bw/day (target MOE of 1000).
f Based on an oral NOAEL of 11.2 mg/kg bw/day (target MOE of 300) (assuming an inhalation absorption factor of 100%).
g With respirator, based on an oral NOAEL of 11.2 mg/kg bw/day (target MOE of 300) (assuming an inhalation absorption factor of 100%).
h Application rate expressed as kg a.e./L.
i Area treated expressed as L/day.

Appendix V Intermediate-Term Exposure Estimates and MOEs with Mid-Level PPE

Crop	Method of Application[a]	Formulation	Rate[b] kg a.e./ha	Area Treated ha/day	Daily Exposure µg/kg/day		Margins of Exposure		
					Dermal[c]	Inhalation[d]	Dermal[e]	Inhalation[f]	Inhalation[g]
Non-cropland (brush control)	Aerial (mixer/loader)	Solution	2.016	490	721.69	22.579	1386	496	4960
	Aerial (applicator)	Solution	2.016	490	136.32	0.9878	7336	11338	NA
	Right-of-way	Solution	2.496	18	357.4	4.236	2798	2044	26 440
	Backpack	Solution	0.0025[h]	150[i]	13.913	0.3327	71 875	33 666	336 661
	Low-pressure handwand	Solution	0.0025[h]	150[i]	3.939	0.2421	253 892	46 254	462 537
	High-pressure handwand	Solution	0.0025[h]	3750[i]	328.596	20.223	3043	554	5538
Non-cropland (broadleaf control)	Right-of-way	Solution	4.416	18	632.32	7.495	1581	1494	14 944
	Right-of-way	Wettable granules	2 242.24	1818	354.82	3.468	2818	3230	32 300
	Backpack	Solution	0.0401[h]	150[i]	223.164	5.336	4481	2099	20 989
		Wettable granules	0.0204[h]	150[i]	117.55	2.759	8507	4059	40 591
	Low-pressure handwand	Solution	0.0401[h]	150[i]	63.176	3.884	15 829	2884	28 836
		Wettable granules	0.0204[h]	150[i]	36.159	2.02	27 656	5543	55 433
	High-pressure handwand	Solution	0.0401[h]	3750[i]	5270.7	324.38	190	35	345
			0.01[h]	3750[i]	1314.4	80.89	761	138	1385
		Wettable granules	0.0204[h]	3750[i]	2781.82	166.14	359	67	674
			0.01[h]	3750[i]	1363.64	81.439	733	138	1375

[a] Mid-level PPE: Coveralls and gloves over a single layer (long pants and long-sleeved shirt), except aerial applicator and mixer/loader – only single layer and gloves.
[b] Rate for high-pressure handwand based on volume of 110 L/ha for broadleaf control and 220 L/ha for brush control; lower rate based on 440 L/ha for broadleaf control (solution), 220 L/ha for wettable granule and 250 L/ha for brush control (solution).
[c] Where dermal exposure µg/kg/day = (unit exposure × area treated × rate) ÷ 70 kg bw.
[d] Where inhalation exposure µg/kg/day = (unit exposure × area treated × rate) 70 kg bw (no respirator).
[e] Based on a dermal NOAEL of 1000 mg/kg bw/day (target MOE of 1000).
[f] Based on an oral NOAEL of 11.2 mg/kg bw/day (target MOE of 300) (assuming an inhalation absorption factor of 100%).
[g] With respirator, based on an oral NOAEL of 11.2 mg/kg bw/day (target MOE of 3000) (assuming an inhalation absorption factor of 100%).
[h] Application rate expressed as kg a.e./L
[i] Area treated expressed as L/day.

Appendix VI Intermediate-Term Exposure Estimates and MOEs with Maximum PPE

Crop	Method of Application[a]	Formulation	Rate[b] kg a.e./ha	Area Treated ha/day	Daily Exposure µg/kg/day		Margins of Exposure	
					Dermal[c]	Inhalation[d]	Dermal[e]	Inhalation w Respirator[f]
Non-cropland areas (brush control)	Aerial (mixer/loader)	Solution	2.016	490	721.69	22.579	1386	4960
	Aerial (applicator)	Solution	2.016	490	136.32	0.9878	7336	NA
	Right-of-way	Solution	2.496	18	310.28	0.328	3223	34 149
	Backpack	Solution	0.0025[h]	150[i]	10.861	0.3327	92 075	336 661
	Low-pressure handwand	Solution	0.0025[h]	150[i]	3.716	0.2421	269 131	462 537
	High-pressure handwand	Solution	0.0025[h]	3750[i]	244.71	20.223	4087	554
Non-cropland areas (broadleaf control)	Right-of-way	Solution	4.416	18	548.96	0.5803	1822	19302
	Right-of-way	Wettable granules	2.24	18	306.38	0.3468	3264	32300
	Backpack	Solution	0.0401[h]	150[i]	174.21	0.5336	5740	20 989
		Wettable granules	0.0204[h]	150[i]	92.02	0.2759	10868	40 591
	Low-pressure handwand	Solution	0.0401[h]	150[i]	59.599	0.3884	16 779	28 836
		Wettable granules	0.0204[h]	150[i]	33.711	0.2021	29 664	55 433
	High-pressure handwand	Solution	0.0401[h]	3750[i]	3925.07	32.438	255	345
			0.01[h,j]	3750[i]	978.82	8.089	1022	1385
		Wettable granules	0.0204[h]	3750[i]	2081.57	16.614	480	674
			0.01[h,j]	3750[i]	1020.38	8.144	980	1375

[a] Maximum PPE: Chemical-resistant coveralls and gloves over a single layer (long pants and long-sleeved shirt), respirator and open mixer/loader except aerial applicator and aerial mixer/loader—only single layer and gloves.

[b] Rate for high-pressure handwand based on volume of 110 L/ha for broadleaf control and 220 L/ha for brush control.

[c] Where dermal exposure µg/kg/day = (unit exposure × area treated × rate) / 70 kg bw.

[d] Where inhalation exposure µg/kg/day = (unit exposure × area treated × rate) / 70 kg bw (with respirator).

[e] Based on a dermal NOAEL of 1000 mg/kg bw/day (target MOE of 1000).

[f] Based on an oral NOAEL of 11.2 mg/kg bw/day (target MOE of 300) (assuming an inhalation absorption factor of 100% with the exception of aerial applicator).

[h] Application rate expressed as kg a.e./L.

[i] Area treated expressed as L/day.

[j] Lower rate based on 440 L/ha for broadleaf control (solution), 220 L/ha for wettable granule and 250 L/ha for brush control (solution).

Appendix VII Site Use Information for Commercial Class Uses for which Dicamba Is Supported by the Technical Registrant and There Have Been Risk Concerns Identified

Crop	Province/ Area Grown (ha)/ Percentage of Crop Treated	Application Rate (g a.i./ha)		Maximum Number of Applications per Year	Minimum Number of Days Between Applications	Identification of Risk Assessment Concerns
		Max. Single	Max. Cumulative			
Use-Site 16—Industrial and Domestic Vegetation Control Non-Food Sites						
Non-crop areas	All provinces/ not applicable/ not applicable	4416	4416[a] (If more than one application is carried out per year, the rate per application is half the maximum single rate or lower)	2[b]	Not specified; assuming 10 days[b]	The occupational exposure assessment indicted that high application rates combined with a long period of application (intermediate term exposure) resulted in target MOEs less than expected MOEs. See Section 4.2.

[a] Based on the label.

[b] Based on use scenario for dicamba in corn (field and sweet).

Appendix VIII Alternatives to Dicamba for Site-Pest Combinations of Commercial Class Products for which Risk Concerns Have Been Identified as of March 2005

Site(s)	Pest	Pest Status / Incidence[a]	Alternative Registered Active Ingredients (resistance management group number)[b,c]	Risk Assessment Concern Identified
Non-crop areas	Broadleaf weeds and brush	minor to major pest / present yearly	Group 2: chlorsulfuron, imazapyr, metsulfuron-methyl Group 4: 2,4-D[d], clopyralid, dichlorprop (premixed with 2,4-D), MCPA[d], picloram, triclopyr[d] Group 5: bromacil[d], simazine Group 7: diuron[d] Group 9: glyphosate Group 11: amitrole Group 22: diquat[d], paraquat[d] Group 27: fosamine ammonium[e] Unknown group: acetic acid	The occupational exposure assessment indicted that high application rates combined with a long period of application (intermediate term exposure) resulted in target MOEs less than expected MOEs. See Section 4.2.

a Data from end-user surveys and PMRA research.

b This is a list of registered alternatives only. The PMRA does not endorse any of the alternatives listed.

c See Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*, for additional details on Herbicide Resistance Management Groups.

d These active ingredients are currently under re-evaluation as per PMRA's previous announcements.

e The re-evaluation of fosamine ammonium is complete (see RRD2004-18).

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